REMARKS

The Office Action mailed on October 15, 2008, has been received, and carefully considered.

The Applicant notes that the Examiner has made the species election requirement final, and again urges reconsideration of the election requirement. Indeed, Applicant submits that the burden is on the Patent Office to show that the various species (bacteria, virus, parasites, fungi) are patentably distinct. The patentable original characteristic of the claim is the attachment of a plurality of controls antigens on a solid support, whatever the microbial antigen is. Moreover the plurality of controls listed in paragraph a)-d) of step 1/ as well as paragraph a) to c) of step 2/ is independent of the kind of microbial antigen. In other words, whatever microbial antigen, the said control antigens and control steps would be the same.

The Examiner has objected to claims 2-12 and 14-34 as allegedly being in improper form and including multiple dependencies in improper form. Applicant's record indicates that the multiple dependencies in the claims were removed by the Preliminary Amendment filed on June 21, 2006. The Examiner is respectfully requested to clarify such objection.

The Applicant has amended the claims to recite the definite article for the noun at the beginning of each claim.

In view of the above, the Applicant requests favorable reconsideration of the objections to the claims.

The rejection of claims 1-12 and 14-34 under 35 U.S.C. 112, second paragraph, is obviated by appropriate amendment in part, and traversed in part.

The term "optionally" has been cancelled from claims 2, 5, 16, 23 and 28.

Furthermore, the term "preferably" and the preferred characteristic recited thereafter have been cancelled from claims 1, 4, 18, 27 and 33.

Also, the term "corresponding" has been cancelled from claim 18.

As to the rejection of claim 1 under 35 U.S.C. 112, second paragraph, Applicant submits that the terms "optionally" and "when applicable" do not render this clam indefinite, for the reasons that follow.

In the preamble of claim 1, it is specified that two cases are contemplated:

(1) the detection of both IgM and IgG, and

(2) the detection of only IgG.

In line 8 of step 1/, the term "optionally" reflects the fact that the third control antigen is not necessarily present when only an immunoglobulin of class G specific to said

microbial antigen is assayed, said third control antigen being necessary only in the event of IgM assay.

In line 2 of paragraph a-, the term "optionally" reflects that the control of the presence of rheumatoid factors is necessary only in the event of IgM assay, because it is responsible for possible false positive results as explained in the specification on page 4, line 15 to page 5, line 3.

In paragraph c- of step 2/, the term "when applicable" means that said condition c- is taken into account when said third control is present, namely in the event of IgM assay as mentioned in paragraph c- of step 2/.

As to Step d- in claim 1, the Examiner contends that it is unclear as to how the method controls the presence of the human serum in the tested sample.

The point of this claimed characteristic is only to specify that, according to the claimed method, it is required to carry out the control of the presence of human serum in the tested sample.

A person skilled in the art knows several methods to control the presence of a human serum in a tested sample. For example, such control can be done by physical measurements such as spectroscopy, but also with other biological means. Besides, an original and preferred embodiment of control of the presence of a human serum is specified in claim 3.

As to claim 1, step 2/, the Examiner submits that it is unclear if Applicant intends the use of the first or second detection substance when the expression "said detection substance" is used.

In response thereto, the Applicant has amended claim 1 so as to recite "said first or/and second detection substance" or "at least one of said first and second detection substance".

In fact, it is clear in reading the claim that a first detection is necessary in the event of an IgG assay and a said second detection substance is necessary in the event of an IgM assay. Besides, it is clear in reading the claim that two cases are contemplated:

(1) the detection of both IgM and IgG; or

(2) the detection of only IgG.

Accordingly, the claimed method comprises the use of both said first and second detection substance or only said second detection substance.

The preamble of claim is objected to. The Examiner argues that there is no correlation step which correlates the *in vitro* serological method for diagnosing microbial agents by immunodetection since no diagnosis of microbial agents appear to be achieved.

In fact, in the preamble of claim 1 it is specified that the diagnosis of microbial agent is made by detection of the

presence of patient immunoglobulins specific to a microbial antigen in a patient serum sample to be tested by detection of an immunological reaction complex between said microbial antigen and said specific class M and/or class G immunoglobulin using a first and/or second detection substance.

Besides, it is mentioned in step 2/ that: "a reaction result between said microbial antigen, said serum sample and said detection substance is taken into account if the control...".

The original steps 1/ and 2/ of the characterizing part of the claim concern preliminary control steps before achieving the said diagnosis by taking into account the result if any other reaction between the said microbial antigen attached to the solid support and the said first and/or second detection substance.

To obviate this rejection, the Applicant has amended to recite the term "preliminary steps" in the preamble.

Claim 3 has been objected to because the Examiner deems it unclear how the second detection substance can cause the fourth control antigen to attach the solid support but does not react with the fourth control antigen.

In fact, the second detection substance does not cause the fourth control antigen to attach to solid support. The

fourth control antigen is attached to the solid support by itself and if the second detection substance is immobilized to the solid support at the spot of the fourth control antigen, this implies that the second detection substance has reacted with a human immunoglobulin attached to the fourth control antigen since the said second substance is specific to human immunoglobulin and said second substance is not capable of reacting with said fourth control antigen. The Examiner's attention is also directed to page 13 of the specification in this regard.

Claims 4, 9, 11, 15, 20 and 31 have been amended to recite proper Markush language.

Claim 7 has been objected to as being multiple dependent upon claim 3. This objection is not well-founded because claim 7 is dependent only on claim 1 (see Preliminary Amendment).

Claim 14 has been amended so as to depend on claim 3 and not claim 1 so as to create sufficient antecedent basis for the fourth control antigen.

Claim 17 has been objected because the Examiner deems it unclear if Applicant intends the use of the first or second detection substance. To the contrary, claim 17 clearly specifies that for a vaccine, only IgG are detected. This is the reason why said immunoglobulin specific to said vaccine

agent (said microbial agent) is an immunoglobulin of class G. Applicant believes that claim 17 is clear and concise to a person of ordinary skill in the art.

The term "threshold" has been replaced by "cut-off value" in claim 21 both terms are the translation of the French original word "seuil".

In view of the above amendments and remarks, Applicant submits that that the rejection of claims 1-12 and 14-34 has been overcome. Favorable reconsideration of the rejection is thus urged.

The rejection of claims 1-12 and 13-34 under 35 U.S.C. 102(b) as being anticipated by Wong et al. (U.S. 5,478,753) is respectfully traversed.

The examiner analyses the claims of the present invention in referring only to the steps of the preamble of the claims and not to the original steps 1) and 2) of the claim 1.

Subsequently, the Examiner analyses the content of the Wong et al. reference without any comparison to the claims steps 1 and 2 of the present invention, and concludes "Therefore Wong et al. teaches the instantly claimed invention."

Indeed, the examiner has not shown where the specific characteristics of claims 1 can be found in the Wong et al, disclosure.

The Applicant submits that the only similarity between Wong et al. and the present invention is the fact that a non-specific class M immunoglobulin is used in both cases.

In Wong et al., however, the non-specific class M immunoglobulin is not initially immobilized on the solid support, while according to the present invention the said third antigen control consisting in a non-specific class M immunoglobulin is bound to the support solid when IgM are tested.

Moreover, in Wong et al., the said non-specific class M immunoglobulin is covalently linked to a non-IgM antibody specific to an infectious agent, which is not the case of the third control antigen according to the present invention.

Furthermore, and most importantly, Wong et al. is entirely silent as to the attachment of a non-specific class G immunoglobulin (first control antigen) and a second control antigen containing DNA/histone complexes.

In Wong et al., the only substance initially immobilized on the solid support is a binding substance ("capture material") selected to specifically bind to a so-called antibody which includes a non-specific IgM covalently linked to a non-IgM antibody.

For the reasons set forth above, the Applicant submits that the presently claimed invention is not taught or

disclosed by the Wong et al. reference. Favorable reconsideration of the rejection under 35 U.S.C. 102(b) is therefore urged.

It is believed that the present application is now in condition for allowance, and an early allowance to this effect is respectfully urged. If any final points remain that can be clarified by telephone, Examiner Hines is encouraged to contact Applicant's attorney at the number indicated below.

Respectfully submitted

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